

Patient Information
FOSAMAX PLUS D[®] (FOSS-ah-max PLUS D)
(alendronate sodium/cholecalciferol)
Tablets

Read the patient information before you start taking FOSAMAX PLUS D¹. Also, read the leaflet each time you refill your prescription, just in case anything has changed. This leaflet does not take the place of discussions with your doctor about your medical condition or treatment. You and your doctor should discuss FOSAMAX PLUS D when you start taking your medicine and at regular checkups.

What is the most important information I should know about FOSAMAX PLUS D?

- **You must take FOSAMAX PLUS D exactly as directed to help make sure it works and to help lower the chance of problems in your esophagus (the tube that connects your mouth and stomach). (See “How should I take FOSAMAX PLUS D?”).**
- **If you have chest pain, new or worsening heartburn, or have trouble or pain when you swallow, stop taking FOSAMAX PLUS D and call your doctor. (See “What are the possible side effects of FOSAMAX PLUS D?”.)**

What is FOSAMAX PLUS D?

FOSAMAX PLUS D is a prescription medicine that contains alendronate sodium and vitamin D₃ (cholecalciferol) as the active ingredients. FOSAMAX PLUS D provides a week's worth of vitamin D₃. Some patients may need more vitamin D than is in FOSAMAX PLUS D. Your doctor may recommend an additional vitamin D supplement.

FOSAMAX PLUS D is used for:

- The treatment of osteoporosis (thinning of bone) in women after menopause. It reduces the chance of having a hip or spinal fracture (break).
- Treatment to increase bone mass in men with osteoporosis.

Improvement in bone density may be observed as early as 3 months after you start taking FOSAMAX PLUS D even though you won't see or feel a difference. For FOSAMAX PLUS D to continue to work, you need to keep taking it.

FOSAMAX PLUS D should not be used to treat vitamin D deficiency.

FOSAMAX PLUS D is not a hormone.

FOSAMAX PLUS D is not for use in premenopausal women.

There is more information about osteoporosis and vitamin D at the end of this leaflet.

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Who should not take FOSAMAX PLUS D?

Do not take FOSAMAX PLUS D if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Cannot stand or sit upright for at least 30 minutes
- Have low levels of calcium in your blood
- Are allergic to FOSAMAX PLUS D or any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before using FOSAMAX PLUS D?

Tell your doctor about all of your medical or dental conditions, including if you:

- **have problems with swallowing**
- **have stomach or digestive problems**
- **have kidney problems**
- **have sarcoidosis, leukemia, lymphoma.** These conditions may cause changes in vitamin D.
- **are pregnant or planning to become pregnant.** It is not known if FOSAMAX PLUS D can harm your unborn baby.
- **are breastfeeding.** It is not known if FOSAMAX PLUS D passes into your milk and if it can harm your baby.

Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take FOSAMAX PLUS D?

- Choose the day of the week that best fits your schedule.
- Take 1 tablet of FOSAMAX PLUS D every week on your chosen day **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take FOSAMAX PLUS D while you are sitting or standing.
- Swallow your FOSAMAX PLUS D tablet with a full glass (6-8 oz) of plain water only.

Do **not** take FOSAMAX PLUS D with:

Mineral water
Coffee or tea
Juice

FOSAMAX PLUS D works only if it is taken on an empty stomach.

Do not chew or suck on a tablet of FOSAMAX PLUS D.

After swallowing your FOSAMAX PLUS D tablet, wait at least 30 minutes:

- before you lie down. You may sit, stand or walk, and do normal activities like reading.
- before you take your first food or drink except for plain water.
- before you take other medicines, including antacids, calcium, and other supplements and vitamins.

Do not lie down until after your first food of the day.

- It is important that you keep taking FOSAMAX PLUS D for as long as your doctor says to take it. For FOSAMAX PLUS D to continue to work, you need to keep taking it.

What should I do if I miss a dose of FOSAMAX PLUS D or if I take too many?

- If you miss a dose, take only 1 FOSAMAX PLUS D tablet on the morning after you remember. Do not take 2 tablets on the same day. Continue your usual schedule of 1 FOSAMAX PLUS D tablet once a week on your chosen day.
- If you think you took more than the prescribed dose of FOSAMAX PLUS D, drink a full glass of milk and call your doctor right away. Do not try to vomit. Do not lie down.

What should I avoid while taking FOSAMAX PLUS D?

- Do not eat, drink, or take other medicines or supplements **before** taking FOSAMAX PLUS D.
- Wait for at least 30 minutes **after** taking FOSAMAX PLUS D to eat, drink, or take other medicines or supplements.
- Do not lie down for at least 30 minutes **after** taking FOSAMAX PLUS D. Do not lie down until **after** your first food of the day.

What are the possible side effects of FOSAMAX PLUS D?

FOSAMAX PLUS D may cause problems in your esophagus (the tube that connects the mouth and stomach). (See “What is the most important information I should know about FOSAMAX PLUS D?”.) These problems include irritation, inflammation, or ulcers of the esophagus, which may sometimes bleed. This may occur especially if you do not drink a full glass of water with FOSAMAX PLUS D or if you lie down in less than 30 minutes or before your first food of the day.

- **Stop taking FOSAMAX PLUS D and call your doctor right away if you get any of these signs of possible serious problems of the esophagus:**
 - **Chest pain**
 - **New or worsening heartburn**
 - **Trouble or pain when swallowing**
- Esophagus problems may get worse if you continue to take FOSAMAX PLUS D.
- Mouth sores (ulcers) may occur if the FOSAMAX PLUS D tablet is chewed or dissolved in the mouth.
- You may get flu-like symptoms typically at the start of treatment with FOSAMAX PLUS D.
- You may get allergic reactions, such as hives or, in rare cases, swelling of your face, lips, tongue, or throat.
- FOSAMAX PLUS D may cause jawbone problems in some people. Jawbone problems may include infection, and delayed healing after teeth are pulled.

- The most common side effect is stomach area (abdominal) pain. Less common side effects are nausea, vomiting, a full or bloated feeling in the stomach, constipation, diarrhea, black or bloody stools (bowel movements), gas, eye pain, rash that may be made worse by sunlight, hair loss, headache, dizziness, a changed sense of taste, joint swelling or swelling in the hands or legs, and bone, muscle, or joint pain.
- **Call your doctor if you develop severe bone, muscle, or joint pain.**
- Some patients have experienced fracture in a specific part of the thigh bone. Call your doctor if you develop new or unusual pain in the hip or thigh.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the side effects with FOSAMAX PLUS D. Ask your doctor or pharmacist for more information.

How do I store FOSAMAX PLUS D?

- Store FOSAMAX PLUS D at 68 to 77°F (20 to 25°C). Protect from moisture and light. Store tablets in the original blister package until time of use.
- Safely discard FOSAMAX PLUS D that is out-of-date or no longer needed.
- **Keep all FOSAMAX PLUS D and all medicines out of the reach of children.**

General information about using FOSAMAX PLUS D safely and effectively

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use FOSAMAX PLUS D for a condition for which it was not prescribed. Do not give FOSAMAX PLUS D to other people, even if they have the same symptoms you have. It may harm them.

This leaflet is a summary of information about FOSAMAX PLUS D. If you have any questions or concerns about FOSAMAX PLUS D or osteoporosis, talk to your doctor, pharmacist, or other health care provider. You can ask your doctor or pharmacist for information about FOSAMAX PLUS D written for health care providers. For more information, call 1-877-408-4699 (toll-free) or visit the following website: www.fosamaxplusd.com.

What are the ingredients in FOSAMAX PLUS D?

Active ingredients: alendronate sodium and cholecalciferol (vitamin D₃).

Inactive ingredients: cellulose, lactose, medium chain triglycerides, gelatin, croscarmellose sodium, sucrose, colloidal silicon dioxide, magnesium stearate, butylated hydroxytoluene, modified food starch, and sodium aluminum silicate.

What should I know about vitamin D?

Vitamin D is an essential nutrient, required for calcium absorption and healthy bones. The main source is through exposure to summer sunlight, which makes vitamin D in our skin. Winter sunlight in most of the United States is too weak to produce vitamin D. Even in the summer, clothing or sun block can prevent enough sunlight from getting through. In addition, as people age, their skin becomes less able to make vitamin D. Very few foods are natural sources of vitamin D. Some foods, such as milk, some brands of orange juice and breakfast cereals are fortified with vitamin D.

Too little vitamin D leads to low calcium absorption and low phosphate. These are minerals that make

bones strong. Even if you are eating a diet rich in calcium or taking a calcium supplement, your body cannot absorb calcium properly unless you have enough vitamin D. Too little vitamin D may lead to bone loss and osteoporosis.

What should I know about osteoporosis?

Normally your bones are being rebuilt all the time. First, old bone is removed (resorbed). Then a similar amount of new bone is formed. This balanced process keeps your skeleton healthy and strong.

Osteoporosis is a thinning and weakening of the bones. It is common in women after menopause, and may also occur in men. In osteoporosis, bone is removed faster than it is formed, so overall bone mass is lost and bones become weaker. Therefore, keeping bone mass is important to keep your bones healthy. In both men and women, osteoporosis may also be caused by certain medicines called corticosteroids.

At first, osteoporosis usually has no symptoms, but it can cause fractures (broken bones). Fractures usually cause pain. Fractures of the bones of the spine may not be painful, but over time they can make you shorter. Eventually, your spine can curve and your body can become bent over. Fractures may happen during normal, everyday activity, such as lifting, or from minor injury that would normally not cause bones to break. Fractures most often occur at the hip, spine, or wrist. This can lead to pain, severe disability, or loss of ability to move around (mobility).

Who is at risk for osteoporosis?

Many things put people at risk of osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who:

- Are going through or who are past menopause

Men who:

- Are elderly

People who:

- Are white (Caucasian) or oriental (Asian)
- Are thin
- Have family member with osteoporosis
- Do not get enough calcium or vitamin D
- Do not exercise
- Smoke
- Drink alcohol often
- Take bone thinning medicines (like prednisone or other corticosteroids) for a long time

What can I do to help treat osteoporosis?

In addition to FOSAMAX PLUS D, your doctor may suggest one or more of the following lifestyle changes:

- **Stop smoking.** Smoking may increase your chance of getting osteoporosis.
- **Reduce the use of alcohol.** Too much alcohol may increase the chance of osteoporosis and injuries that can cause fractures.

- **Exercise regularly.** Like muscles, bones need exercise to stay strong and healthy. Exercise must be safe to prevent injuries, including fractures. Talk with your doctor before you begin any exercise program.
- **Eat a balanced diet.** Having enough calcium in your diet is important. Your doctor can advise you whether you need to change your diet or take any dietary supplements, such as calcium or additional vitamin D.

Rx only

Manuf. for: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

By:
FROSST IBERICA, S.A.
28805 Alcalá de Henares
Madrid, Spain

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